



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorneys Docket No.: 40072-0008

Applicants: Shin-ichi KITAHARA, et al.

Confirmation No.: 7416

Appl. No.: 10/500,157

Group Art Unit: 1624

Filed: June 25, 2004

Examiner: Bruck Kifle

Title: NOVEL CRYSTALLINE TRICYCLIC TRIAZOLOBENZAZEPINE  
DERIVATIVE

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Shin-ichi KITAHARA, the undersigned, do hereby declare:

1. THAT I am a co-inventor of the invention described and claimed  
in the above patent application.

2. THAT the following experiments were conducted under my  
direction and control:

(1) Preparation of crystalline compound of USP 6,372,735  
2-(1-isopropoxycarbonyloxy-2-methylpropyl)-7,8-dimethoxy-4(  
5H),10-dioxo-2H-1,2,3-triazolo[4,5-c][1]benzazepine was  
prepared in the same manner as described in column 42, line 16  
to column 43, line 34 of USP 6,372,735. The same preparation  
process was repeated three times to obtain three samples, Samples



I, II and III.

(2) Powder X-ray diffraction

Samples I, II and III thus obtained above were evaluated by a powder X-ray diffraction device. Measuring conditions were the same as described in the specification of the above application on page 6, lines 5 to 12. The powder X-ray diffraction patterns of Samples I, II and III are shown in the attached sheets. Further, the characteristic peaks of these samples are as follows:

Sample I:  $4.7 \pm 0.1^\circ$ ,  $10.6 \pm 0.1^\circ$ ,  $12.7 \pm 0.1^\circ$ ,  $18.7 \pm 0.1^\circ$   
Sample II:  $4.7 \pm 0.1^\circ$ ,  $10.6 \pm 0.1^\circ$ ,  $12.8 \pm 0.1^\circ$ ,  $18.7 \pm 0.1^\circ$   
Sample III:  $4.6 \pm 0.1^\circ$ ,  $10.9 \pm 0.1^\circ$ ,  $12.3 \pm 0.1^\circ$ ,  $18.9 \pm 0.1^\circ$

(3) Differential scanning calorimetry (DSC)

Samples I, II and III thus obtained above were evaluated with DSC. Measuring conditions were the same as described in the specification of the above application on page 6, lines 22 to 28. The DSC charts of Samples I, II and III are shown in the attached sheets. According to the charts, the melting points of these samples are considered as follows:

Sample I:

The sample had one endothermic peak at  $220^\circ\text{C}$  with an onset temperature of  $200^\circ\text{C}$  and a termination temperature of  $228^\circ\text{C}$ . Thus, the melting point of the sample crystalline compound is in the range of  $200^\circ\text{C}$  to  $228^\circ\text{C}$  (with decomposition).

Sample II:

The sample had one endothermic peak at  $222^\circ\text{C}$  with an onset temperature of  $200^\circ\text{C}$  and a termination temperature of  $229^\circ\text{C}$ . Thus, the melting point of the sample crystalline compound is in the range of  $200^\circ\text{C}$  to  $229^\circ\text{C}$  (with decomposition).

Sample III:

The sample had one endothermic peak at  $222^\circ\text{C}$  with an onset temperature of  $199^\circ\text{C}$  and a termination temperature of  $229^\circ\text{C}$ .



Thus, the melting point of the sample crystalline compound is in the range of 199°C to 229°C (with decomposition).

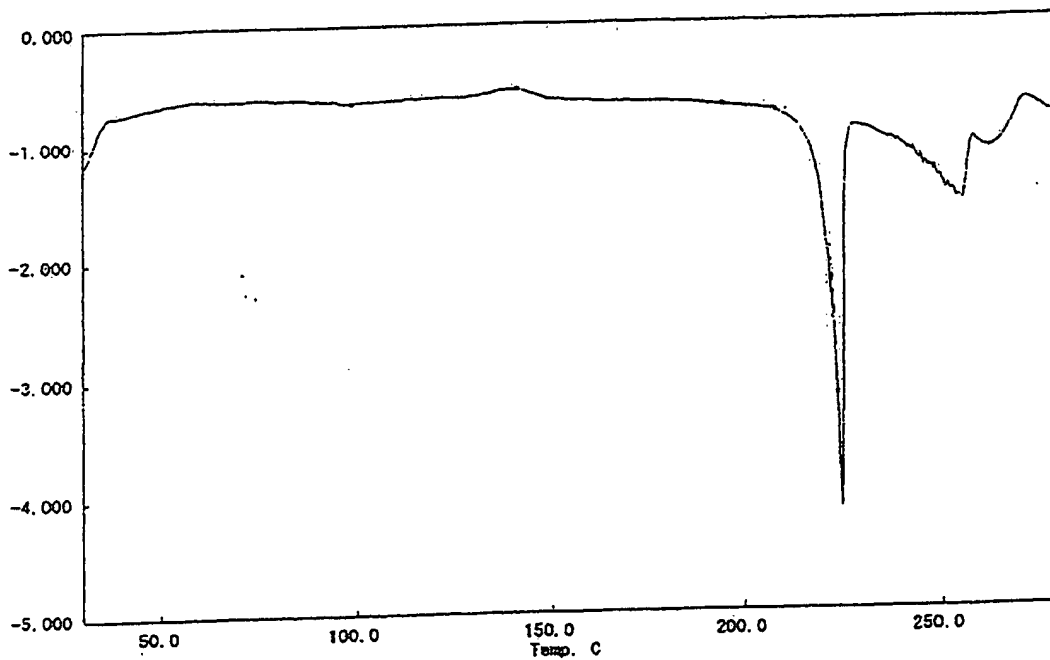
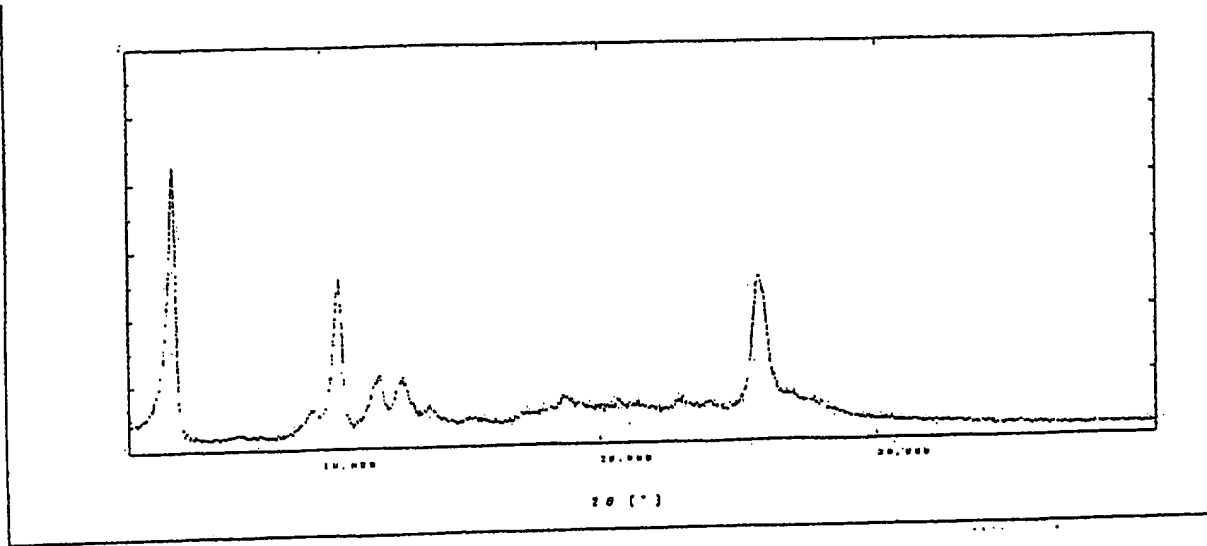
3. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

April 20, 2005  
Date

Shin-ichi Kitahara  
Shin-ichi KITAHARA

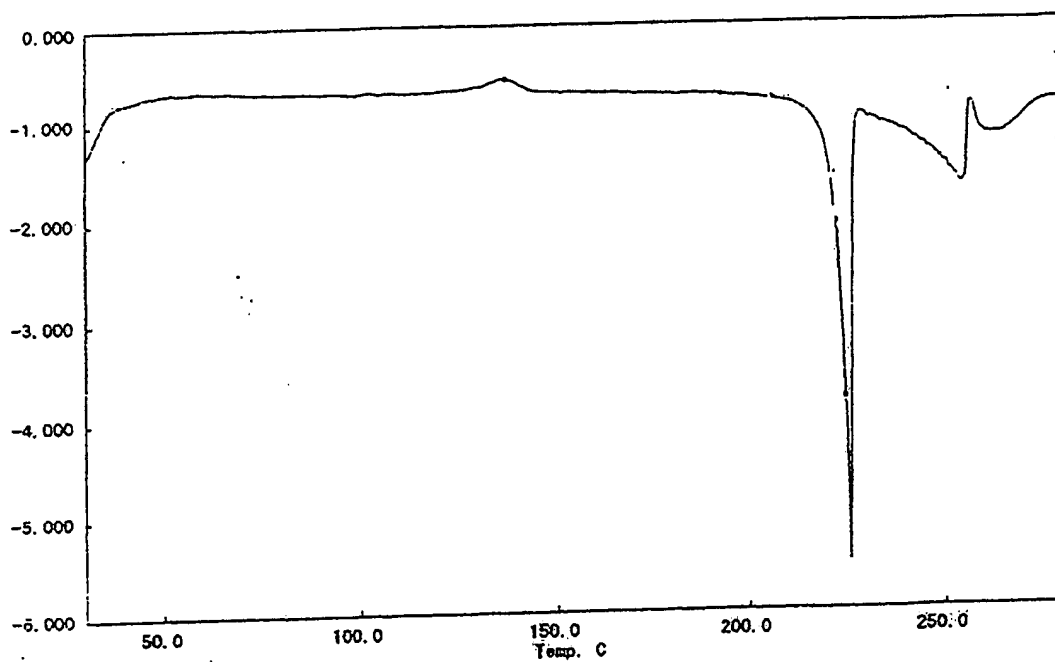
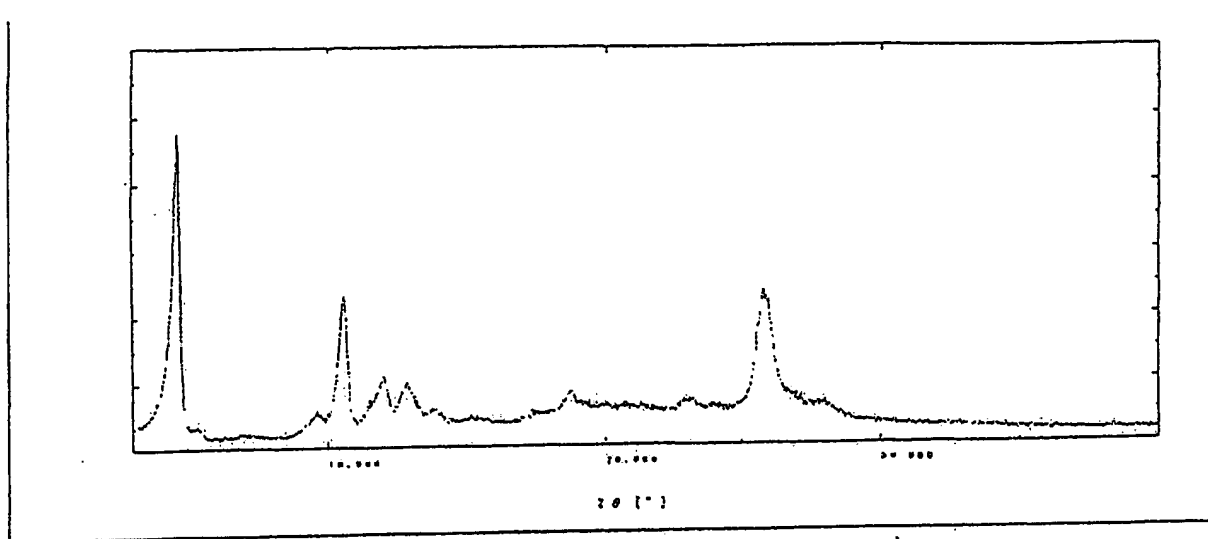


I





II





III

